REMARKS

This response addresses the issues raised by the Examiner in the Office Action mailed May 18, 2004. Initially, Applicants would like to thank the Examiner for the careful consideration given in this case. Claim 1 has been currently amended and new Claim 6 has been added. No new matter has been added by these amendments. Thus, Claims 1 and 3-6 are pending in this case all to more clearly and distinctly claim Applicants' invention. Applicants respectfully request entry of the amendments as they place the application in condition for allowance or in better condition for possible appeal.

New Claim 6 claims an integral multilayer analytical element, wherein a ratio of the pore diameter of the uppermost porous membrane to the pore diameter of the just underlying porous membrane is in a range of 0.01 to 0.5 μm. Support for this amendment appears for example, in the specification at page 7, line 13. Accordingly, it is respectfully submitted that no new matter has been added by the amendments.

Rejection Based On Yaginuma Under 35 U.S.C. § 103 (a)

The Examiner rejects Claims 1 and 3-5 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,008,078 to Yaginuma et al as applied to Claims 1 and 3-5 and new Claim 6. Applicants respectfully traverse this rejection.

The Examiner acknowledges that Yaginuma does not teach the improvement that the liquid blocking layer is composed of at least two porous membrane layers. However, the Examiner then asserts that Yaginuma states that there is a danger that liquids, especially liquids which contain interfering substances such as alkaline materials in solution, will pass through the barrier layer as a result of capillary action within the voids in the case of air barrier layers made of porous materials. The Examiner then states that the air barrier layer is preferably hydrophobic or water repellent to the extent that capillary flow due to the above

mentioned capillary action does not occur. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify the multi-layer analysis of Yaginuma to incorporate another air barrier layer to add an extra level of protection against liquid migration through to the indicator layer and render the multi-layer useless. Applicants respectfully disagree with the Examiner.

Currently amended Claim 1 claims an integral multilayer analytical element for the determination of ammonia or an ammonia-producing substance comprising a transparent support, an indicator layer containing an indicator which produces a detectable change by gaseous ammonia, a liquid blocking layer permitting gaseous ammonia to pass therethrough, a reagent layer containing an alkaline buffering agent and optionally a reagent capable of reacting with said ammonia-producing substance to produce ammonia, and a spreading layer, adhesively laminated in this order, the improvement which comprises that said liquid blocking layer is composed of at least two types of porous membrane layers which are impermeable to aqueous liquids, wherein a pore diameter of an uppermost porous membrane of said at least two types of porous membrane layers, which contacts said reagent layer, is smaller than that of a just underlying porous membrane.

To establish obviousness of a claimed invention, all claim elements must be disclosed, taught or suggested by the prior art. Although Yaginuma discloses an integral multi-layer analysis element comprising a transparent support, an indicator layer, a liquid permeation barrier layer, a reagent layer and a spreading layer, adhesively laminated in this order, we agree with the Examiner that Yaginuma does not teach that the liquid blocking layer of the present invention is composed of at least two porous membrane layers. Further, Yaginuma does not teach that the top membrane that contacts the reagent layer has pores with a diameter that is smaller than the just underlying member.

Yaginuma teaches two types of barrier layers: an air barrier layer and a polymer barrier layer. The air barrier in Yaginuma consists of a porous material with connected pores in which a layer of air functions as a barrier layer. The polymer barrier layer consists of a thin homogenous, nonporous layer of hydrophobic polymer. See Yaginuma at Col. 6, lines 14-23. Since both types of barrier layers do not pass aqueous liquids, they are fundamentally hydrophobic or water repellent.

In the Office Action, the Examiner argues that Yaginuma teaches that there is a danger that liquids, especially liquids which contain interfering substances such as alkaline materials in solution, will pass through the barrier layer as a result of capillary action within the voids in the case of air barrier layers made of porous materials. The Examiner then states that the air barrier layer is preferably hydrophobic or water repellent to the extent that capillary flow due to the above mentioned capillary action does not occur. However, here Yaginuma merely teaches that the barrier layer must be hydrophobic or water repellent so that capillary flow does not occur. Yaginuma does not teach the necessity that the liquid blocking layer is composed of at least two porous membrane layers.

In contrast, the present invention claims a liquid blocking layer composed of at least two porous membrane layers which are impermeable to aqueous liquids and is characterized in that the diameter of the pores in the uppermost membrane, which contact the reagent layer, is smaller than that of the just underlying membrane. Yaginuma does not disclose having at least two porous membranes in the barrier layer with different pore diameters. The present invention requires that at least two types of porous membrane layers which are impermeable to aqueous liquids comprise the liquid blocking layer. Further, the present invention requires that the pore diameter in an uppermost porous membrane of at least two types of porous membrane layers that contacts the reagent layer is smaller than that of a just underlying porous membrane. Yaginuma does not teach any motivation or advantage of this

arrangement employed in the present invention.

In addition, the advantages of the present invention are shown in the Examples. Comparative Example 1 shows a porous membrane having a thickness of 25 μm and a liquid-blocking layer having a pore diameter of 0.1 μm was used as the liquid-blocking layer (Table 1) and an increase on optical density from 0.34 to 0.76, i.e. 0.42, with the increase of ammonia nitrogen concentration from 0 to 400 μg/dl and coefficient for variation of 8.1%, 3.5 %, 5.2 % i.e. 5.6% on the average were obtained. See Table 2. In contrast, Example 1 shows two porous membranes, one having a thickness of 9 μm and a pore diameter of 0.1 μm (Layer 1) and other having a thickness of 7 μm and a pore diameter of 1-3 μm (Layer 2) were used as the liquid blocking layer (Table 1) i.e. a total thickness is 16 μm, and an increase of optical density from 0.39 to 0.99, i.e. 0.60, with the increase of ammonia nitrogen concentration from 0 to 400 μg/dl and coefficient for variation of 2.2%, 2.0%, 1.3%, i.e. 1.8 on the average were obtained. See Table 2. This shows that in the present invention, sensitivity is increased about 1.4 times (0.60/0.42) and accuracy is improved about 3 times (5.6%/1.8%) and the thickness is thinned from 25 μm to 16 μm. These effects are obtained by substituting the lower portion of the porous membrane in Comparative Example 1 with a porous membrane having a greater pore diameter is not obvious. Note that when a porous membrane having a pore diameter of 1-3 μm which is similar to Layer 2 in Example 1, it did not work as expected, and the solution spotted to the reagent layer reached the indicator layer. See page 16, lines 11-13. Further the barrier layer employed in the examples in Yaginuma has a thickness of 170 μm (Column 17, line 1), which is much thicker that the present invention, about 10 times that of the liquid blocking layer in Example 1 of the present invention.

Thus, the Applicants believe that the present invention is not obvious over the teaching of Yaginuma since Yaginuma does not teach, disclose or suggest the present claims.

Moreover, one skilled in the art would find nothing in Yaginuma that would disclose, teach or suggest the claimed invention or any reason for making it. Therefore, an obvious rejection under 35 U.S.C. §103 (a) is improper.

In view of the remarks presented herein, it is respectfully submitted that the present application is in condition for final allowance and notice to such effect is requested. If the Examiner believes that additional issues need to be resolved before this application can be passed to issue, the undersigned invites the Examiner to contact him at the telephone number provided below.

Respectfully submitted,

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By _____

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